(original and update), and verification audit; names of the person(s) who completed the self-assessment, verification audit, risk factor study (baseline report), risk factor study (update), and action plan; signature of the program manager; and date the form was completed. Form FDA 3520 requires the name and address of the jurisdiction, contact information for the enrollee's designated contact person, completion date of the self-assessment, date of the verification audit report, name of the auditor, signature of the official completing the form, and date the form was completed.

The reporting burden in table 5 of this document includes only the time necessary to fill out and send the forms, as compiling the underlying information (including self-assessment reports, baseline surveys, outside audits, and supporting documentation) is accounted for under the recordkeeping estimates in table 4 of this document.

In the **Federal Register** of February 3, 2014 (79 FR 6200), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Form FDA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of "FDA National Registry Report".	3519	500	1	500	0.1 (6 minutes)	50
Submission of "Permission to Publish in National Registry".	3520	500	1	500	0.1 (6 minutes)	50
Request for Documentation of Successful Completion of Staff Training.	Conference for Food Protection Training Plan and Log.	500	3	1,500	0.1 (6 minutes)	150
Total						250

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimates of the number of respondents and the hours per response on its experience with the Program Standards over the past 14 years. As explained previously in this document, FDA estimates that no more than 500 regulatory jurisdictions will participate in the Program Standards in any given year. FDA estimates a total of 12 minutes annually for each enrolled jurisdiction to complete both forms. FDA bases its estimate on the small number of data elements on the two forms and the ease of availability of the information. FDA estimates that annually 500 regulatory jurisdictions will submit one Form FDA 3519 for a total of 500 annual responses. Each submission is estimated to take 0.1 hour (6 minutes) per response for a total of 50 hours. FDA estimates that annually 500 regulatory jurisdictions will submit one Form FDA 3520 for a total of 500 annual responses. Each of these submissions is estimated to take 0.1 hour (6 minutes) per response for a total of 50 hours. FDA estimates that annually 500 regulatory jurisdictions will submit 3 requests for documentation of successful completion of staff training using the CFP Training Plan and Log for a total of 1,500 annual responses. Each submission is estimated to take 0.1 hour (6 minutes) per response for a total of 150 hours. Thus, the total reporting burden for this information collection is 250 hours.

Dated: May 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0639]

Agency Information Collection Activities; Proposed Collection; Comment Request; Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the eligibility criteria and the process to be followed by establishments when notifying FDA of a manufacturer's intent to have an accredited third party conduct a quality systems regulation inspection of their establishment instead of FDA, under the Accredited Persons (AP) Inspection Program.

DATES: Submit either electronic or written comments on the collection of information by July 28, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the

public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program (Formerly Requests for Inspection Under the Inspection by Accredited Persons Program)—(OMB Control Number 0910–0569)—Extension

Section 201 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) amended section 704 of the Federal Food, Drug, and Cosmetic Act by adding subsection (g) (21 U.S.C. 374(g)). This amendment authorized FDA to establish a voluntary third-party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. In 2007, the program was modified by the Food and Drug Administration Amendments Act of 2007 by revising eligibility criteria and by no longer requiring prior approval by FDA. To reflect the revisions, FDA modified the title of the collection of information and on March 2, 2009, issued a guidance entitled ''Manufacturer's Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007.'' This guidance supersedes the Agency's previous guidance regarding requests for third-party inspection and may be found on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm*. This guidance is intended to assist device establishments in determining whether they are eligible to participate in the AP Program and, if so, how to submit notification of their intent to use the program. The AP Program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP Program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible to participate in the AP Program. Further, 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP Program. Based on communications with industry, FDA estimates that on an annual basis approximately 20 of these manufacturers may use an AP in any given year.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 U.S.C. section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification regarding use of an accredited person—374(g)	20	1	20	15	300

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0604]

Electronic Submission of Postmarketing Safety Reports Involving Vaccine Products; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Biologics Evaluation and Research (CBER) in the Food and Drug Administration (FDA) is announcing a pilot project to evaluate its current systems for receiving postmarketing safety reports involving vaccine products electronically for processing into the Vaccine Adverse Event Reporting System (VAERS). As part of this pilot project, CBER also plans to assess the updated International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E2B(R3) specification for electronic transmission of vaccine Individual Case Safety Reports (ICSRs). Participation in the pilot project is open to firms that submit postmarketing reports into VAERS. CBER plans to accept participation from up to six applicants. The pilot project is intended to provide industry and CBER regulatory review staff with an opportunity to evaluate current system capabilities for sending and receiving postmarketing safety reports for vaccine products using FDA's Electronic Submissions Gateway (ESG), including the use of the updated ICH E2B(R3) specification.

DATES: Submit an electronic request to participate in this pilot project by June 27, 2014.

ADDRESSES: If you are interested in participating in this pilot project, you should submit an electronic request to *CBER_eSubmitter_program@fda.hhs.gov*.